Before the
Federal Communications Commission
Washington, D.C. 20554

ET Docket No. 92-255

In the Matter of

Amendment of Part 18 to Remove Unnecessary Regulations Regarding Magnetic Resonance Systems — RM-7903

NOTICE OF PROPOSED RULE MAKING

Adopted: November 4, 1992; Released: December 7, 1992

Comment Date: March 1, 1993
Reply Comment Date: March 31, 1993

By the Commission:

INTRODUCTION

1. By this action, the Commission proposes to amend Part 18 of its rules to remove regulations that unnecessarily increase the amount of time and money required to bring new non-consumer, medical magnetic resonance (MR) systems to market. These systems are used by medical professionals to study the molecular structure of a patient for diagnostic and monitoring purposes. This proposal addresses a petition for rule making filed by the National Electrical Manufacturers Association on January 29, 1992.

BACKGROUND

2. Part 18 of the rules sets forth requirements designed to minimize the potential for interference to radio and TV services by industrial, scientific and medical (ISM) equipment.[1] Such equipment generates radio frequency (RF) energy in order to perform a non-communications related function. Common examples of consumer ISM equipment include microwave ovens and RF lighting devices. Examples of non-consumer ISM equipment include industrial heaters, RF stabilized arc welders and magnetic resonance equipment. Before ISM equipment can be marketed in the United States, it must comply with the technical standards and equipment authorization procedures specified in Part 18.

3. On January 29, 1992, the National Electrical Manufacturers Association (NEMA) filed a petition for rule making requesting that the Commission amend Part 18 to exempt medical magnetic resonance systems from the technical standards and authorization requirements.[2] MR systems generate radio signals, typically in the HF or low VHF range, below 64 MHz, in order to produce images of body organs. NEMA states that MR systems pose little risk of interference. It notes that MR systems must be capable of detecting very weak radio signals. Therefore, MR systems are shielded against outside radio noise. This same shielding prevents radiation of the radio signals generated by MR systems to the outside environment. NEMA states that it is unaware of any reported instances of interference caused by MR systems. NEMA argues that the required testing is costly and disruptive because it must of necessity be performed in a hospital or health care facility. NEMA notes that in 1986, under similar circumstances, the Commission exempted medical ultrasonic equipment from Part 18 technical standards and authorization requirements.[3]

4. Seven parties filed comments on NEMA's petition.[4] All of the commenters support NEMA's petition. However, Hewlett Packard Company Medical Products Group (HP) urges the Commission to proceed cautiously. HP states that hospital electrocardiogram (ECG) telemetry systems operating in the 450-470 MHz band have experienced interference. HP suggests further investigation is needed to determine whether MR systems have been a source of such interference. In reply, NEMA states that, in view of the wide separation of the frequencies used, there is little reason to suspect MR systems are causing interference to ECG systems.

DISCUSSION

5. As indicated in NEMA's petition, it appears that MR systems pose little risk of interference because of the way they are designed and installed. We also note that there are relatively few installations of MR systems (under 1000), and in the event that measures needs to be taken to correct interference, the locations of the equipment are known.[5] While we appreciate HP's concern about interference to ECG systems, there does not appear to be a basis for identifying MR systems as a likely source of that interference. We also recognize that the authorization requirement is burdensome and costly for MR systems. Given the low volume production of MR systems, this can significantly affect the unit cost of each system, contributing to the increasing costs of medical care.

6. We agree with NEMA that the circumstances presented here are similar to those that led us earlier to exempt non-consumer medical ultrasonic equipment from Part 18 rules. We are unaware of any interference that resulted from the medical ultrasonic equipment exemption. On balance, we tentatively conclude that the costs of our technical standards and authorization requirements for MR

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[1] *See* 47 C.F.R. Section 18.101, *et seq.*

[2] *See* Petition for Rulemaking of the Magnetic Resonance Section of the National Electrical Manufacturers Association, RM-7903. MR Systems are subject to verification of compliance by their manufacturers. *See* 47 C.F.R. Section 18.203(b). Under the verification requirement, the manufacturer must test the product, retain a copy of the test report and place a label on the product. *See* 47 C.F.R. Section 2.902. Submittal of information to the Commission is required only upon request.

[3] See *Report and Order*, General Docket No. 85-303, 1 FCC Rcd 553 (1986).

[4] Comments were filed by Bruker Medical Imaging, Inc.; General Electric Medical Systems; Hewlett-Packard Company; Philips Medical Systems; Picker International, Inc.; Siemens Medical Systems, Inc.; and Toshiba America MRI, Inc.

[5] U.S. Food and Drug Administration rules require manufacturers to maintain a product locator file for MR systems.

systems are unwarranted given the low risk of interference. Accordingly, we are proposing to amend Part 18 to exempt MR systems from the technical standards and authorization requirements that now apply to that equipment. We will, of course, continue to apply the requirements of Section 18.111(b) that operators of MR Systems correct any harmful interference that may occur. The proposed rule changes are set forth in the Appendix B.

PROCEDURAL MATTERS

7. *Ex Parte Rules - Non-Restricted Proceeding.* This is a non-restricted notice and comment rule making proceeding. *Ex parte* presentations are permitted, except during the Sunshine Agenda period, provided they are disclosed as provided in Commission rules. *See generally* 47 CFR Sections 1.1202, 1.1203, and 1.1206(a).

8. *Regulatory Flexibility Act.* As required by Section 603 of the Regulatory Flexibility Act, the Commission has prepared an Initial Regulatory Flexibility Analysis (IRFA) of the expected impact on small entities of the proposals suggested in this document. The IRFA is set forth in Appendix A. Written public comments are requested on the IRFA. These comments must be filed in accordance with the same filing deadlines as comments on the rest of the Notice, but they must have a separate and distinct heading designating them as responses to the Initial Regulatory Flexibility Analysis. The Secretary shall send a copy of this Notice of Proposed Rule Making, including the Initial Regulatory Flexibility Analysis, to the Chief Counsel for Advocacy of the Small Business Administration in accordance with paragraph 603(a) of the Regulatory Flexibility Act. Pub. L. No. 96-354, 94 Stat. 1164, 5 U.S.C. Section 601 *et seq.* (1980).

9. *Comment Dates.* Pursuant to the applicable procedures set forth in Sections 1.415 and 1.419 of the Commission's Rules, 47 CFR Sections 1.415 and 1.419, interested parties may file comments on or before **March 1, 1993** and reply comments on or before **March 31, 1993.** To file formally in this proceeding, you must file an original and four copies of all comments, reply comments, and supporting comments. If you want each Commissioner to receive a personal copy of your comments, you must file an original plus nine copies. You should send comments and reply comments to Office of the Secretary, Federal Communications Commission, Washington, DC 20554. Comments and reply comments will be available for public inspection during regular business hours in the Dockets Reference Room (Room 239) of the Federal Communications Commission, 1919 M Street, N.W., Washington, D.C. 20554.

10. For further information on this proceeding, contact Mr. Errol Chang, Technical Standards Branch, Office of Engineering and Technology, (202) 653-7316.

FEDERAL COMMUNICATION COMMISSION

Donna R. Searcy

Donna R. Searcy
Secretary

APPENDIX A

INITIAL REGULATORY FLEXIBILITY ANALYSIS

Reason for Action: This rule making proceeding is initiated to obtain comment on whether the Commission's technical standards and authorization requirements regarding magnetic resonance equipment are necessary.

Objective: The Commission seeks to remove regulations regarding magnetic resonance equipment that appear unnecessary in order to enable advanced medical devices to be brought to market faster and more efficiently.

Legal Basis: The action proposed is authorized under Sections 4(i), 302, 303(g) and 303(r) of the Communication Act of 1934, as amended, 47 U.S.C. Sections 154(i), 302, and 303(r).

Reporting, Recordkeeping and Other Compliance Requirements: None.

Federal Rules which Overlap, Duplicate or Conflict with These Rules: None

Description, Potential Impact and Number of Small Entities Involved: This action would relieve manufacturers and importers of magnetic resonance equipment used for medical diagnosis and monitoring of the responsibility to meet Commission testing and record keeping requirements. We estimate that there are no more than 20 such entities.

Any Significant Alternatives Minimizing the Impact on Small Entities Consistent with Stated Objective: None

APPENDIX B

Part 18 of Title 47 of the Code of Federal Regulations is proposed to be amended as follows:

PART 18 - INDUSTRIAL, SCIENTIFIC, AND MEDICAL EQUIPMENT

1. The authority citation for Part 18 continues to read as follows:

AUTHORITY: 47 U.S.C. 4, 301, 302, 303, 304 and 307.

2. Section 18.107 is revised by adding a new paragraph (j) to read as follows:

Section 18.107 Definitions.

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(j) *Magnetic resonance equipment.* A category of ISM equipment in which RF energy is used to create images and data representing spatially resolved density of transient atomic resonances within an object.

3. Section 18.121 is revised to read as follows:

Section 18.121 Exemptions.

Non-consumer ultrasonic equipment, and non-consumer magnetic resonance equipment, that is used for medical diagnostic and monitoring applications is subject only to the provisions of Section 18.105, Sections 18.109 through 18.119, and Section 18.303 of this Part.